Invivo

FEB 2 2 2013

Section 5 510(k) Summary

1. SUBMITTER INFORMATION

Establishment / Sponsor Name: Invivo Corporation
Establishment / Sponsor Address: 12151 Research Parkway
Orlando, FL 32826 USA

Manufacturer Name: Philips Medical Systems
Manufacturer Address: 3000 Minuteman Road
Andover, MA 01810

Company Phone: (407) 275-3220

Company Fax: (407) 249-2022

Person to contact regarding questions: Rusty Kelly
Sr. Quality & Regulatory Manager, Invivo Corporation
(407) 455-6166
Rusty.Kelly@philips.com

Establishment Registration Number: 1051786 (Sponsor)
1217116 (Manufacturer)

Date Summary Prepared: August 16th, 2012

2. MODIFIED DEVICE IDENTIFICATION

Trade / Proprietary Name: MRI Patient Monitoring System (Model 865214)

Common name: MRI Patient Monitoring System

Classification name: Cardiac monitor (including cardiotachometer and rate alarm)
(21 CFR 870.2300, Product Code MWI)

3. IDENTIFICATION OF LEGALLY MARKETED CLEARED DEVICE

The MRI Patient Monitoring System (Model 865214) is substantially equivalent to the following cleared device:

Cleared Device	Manufacturer	510(k) No.	Clearance Date
MRI Patient Monitoring System (Model 865214)	Invivo Corporation	K090785	Dec 15, 2009

4. MODIFIED DEVICE DESCRIPTION

The modified device, MRI Patient Monitoring System (Model 865214), is substantially equivalent to the cleared device.

Invivo has marketed the cleared device, MRI Patient Monitoring System (Model 865214), since 2009. Invivo identified the opportunity to reduce healthcare costs by replacing the current temperature option which is an Ethylene Oxide (EO) sterilized single-use temperature sensor with a reusable temperature sensor that utilizes single-use gamma irradiated sterilized jackets (sheath).

The modified device, MRI Patient Monitoring System (Model 865214) and the previously cleared device, also identified as MRI Patient Monitoring System (Model 865214) which received clearance to market under 510(k) K090785 on December, 15 2009, are identical with respect to indications for use, intended use, fundamental scientific technology, software architecture and design. Both devices are multi-parameter patient monitors intended for use by healthcare professionals to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. Both devices provide patient monitoring data for ECG, SpO2, respiration, non-invasive blood pressure (NIBP), invasive blood pressure (IBP), temperature, oxygen (O2), end-tidal carbon dioxide (EtCO2), and anesthetic agents.

The modifications to the previously cleared device are only in regards to the temperature parameter. The primary differences between the MRI Patient Monitoring System (Model 865214) and the previously cleared device are listed below:

- Body temperature measurement is completed with a reusable sensor that is covered with a sterilized jacket (sheath)(rather than a single-use sterilized sensor).
- Sterilization method is Gamma Radiation (rather than Ethylene Oxide (EO)).
- The reusable sensor is not sterilized. Labeling of the sensor including the instructions for use (IFU) identify the need to use a sterile jacket (sheath).
- Product labeling and the IFU have been updated to reflect the modifications accordingly

The differences between the modified device, MRI Patient Monitoring System (Model 865214) and the previously cleared device are explained in greater detail in Section 12, the Substantial Equivalence Discussion, which includes a comparison table.

5. INTENDED USE

The intended use of the modified device, as described in its labeling, has not changed from that of the cleared device as a result of the modification.

The MRI Patient Monitoring System (Model 865214) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals.

6. FUNDAMENTAL SCIENTIFIC TECHNOLOGY SUMMARY

The fundamental scientific technology employed in the operation of the MRI Patient Monitoring System (Model 865214) as modified, has not changed from that of the previously cleared device as a result of the modification. A detailed explanation of the fundamental scientific technology is provided in Section 11 of this submission.

7. NON-CLINICAL PERFORMANCE DATA SUMMARY

The performance data referenced in this submission establishes substantial equivalence of the modified device, the MRI Patient Monitoring System (Model 865214), to the previously cleared device which received market clearance on December 15th, 2009 in 510(k) K090785. The modified device was evaluated to the following safety and performance tests:

I. Voluntary standards
II. Verification and validation of performance specifications
III. Verification and validation of MR conditions of use

In all testing, the device was verified using a worst-case environment.

I. Voluntary Standards

The MRI Patient Monitoring System (Model 865214) was evaluated to the following voluntary standards where applicable to the modifications per FDA Guidance titled *"Use of Standards in Substantial Equivalence Determination"*. Standards are listed in Section 1 of the CDRH Premarket Review Submission Cover Sheet included in this submission. A declaration of conformity to the recognized consensus standards is included in Section 9 of this submission with a Standards Summary Report Table noting deviations and adaptions. Additionally, the Standards Data Reports for 510(k) for each voluntary standard (based on Form FDA 3654 (09/07)) is included in Section 21 of this submission.

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

- IEC 60601-1-6, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Usability
- IEC 60601-2-49, Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ASTM E1112-00, Standard specification for electronic thermometer for intermittent determination of patient temperature
- ISO 14971, Medical devices – Application of risk management to medical devices
- ASTM F2503–08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2052-06, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- BS EN 12470-4, Clinical thermometers. Performance of electrical thermometers for continuous measurement
- ISO 10993-1, Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process
- ISO 10993-5, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity

The results of the testing performed in accordance with the Voluntary Standards listed above demonstrated that the modified device is as safe and effective as the previously cleared device. Evidence of this is documented in Section 18 of this submission.

II. Verification and Validation of Performance Specifications

Temperature measurement parameters of the MRI Patient Monitoring System (Model 865214) were verified according to the performance specifications defined by Invivo Corporation according to national standards, international standards, market needs, risk management, and intended use. The Verification and Validation Protocol for the specifications which are modified from the cleared device are provided in Section 18 of this submission.

Results of the complete verification and validation indicate that the modified device operates as intended within the performance specifications. The results do not raise issues regarding the safety and effectiveness of the device and clinical data was not required to substantiate claims of safety and effectiveness.

Verification and validation of the other vital sign measuring parameters were not required because the modifications made to the cleared device were only in regards to the temperature parameter.

III. Verification and Validation of MRI Conditions of Use

The MR conditions of use of the modified device are defined by Invivo Corporation according to national standards, international standards, intended use, risk management, and market needs. The modified device's reusable temperature sensor was evaluated for magnetically induced displacement force, proton emissions, image artifact, and RF heating. Details are provided in Section 18.

Test results demonstrate that the MRI Patient Monitoring System (Model 865214) meets the MR conditions of use as defined in the modified device labeling.

8. CONCLUSION OF SUBSTANTIAL EQUIVALENCE

The modified device, described in this submission is substantially equivalent to the previously cleared device. This conclusion is based on the guidance provided in the FDA Guidance Documents:

- Deciding When to Submit a 510(k) for a Change to an Existing Device (Issued January 10, 1997),
- Draft Guidance: 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device (Issued July 27, 2011), and
- 510(k) "Substantial Equivalence" Decision Making Process (last updated April 25, 2009)
- Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers

The modifications do not affect the indications for use. Clinical data was not necessary to establish safety and effectiveness for the purpose of substantial equivalence of the previously cleared device, and design validation did not raise new questions regarding the safety and effectiveness of the modified device. Design and labeling modifications do not raise new safety or effectiveness questions. Performance data is available throughout Section 18 to support our claims of safety and effectiveness, and determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Invivo Corporation
c/o Mr. Jeff D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Dr.
Research Triangle Park, NC 27709

Re: K124061
Trade/Device Name: MRI Patient Monitoring System (Model 865214)
Regulation Number: 21 CFR §870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MWI
Dated: January 30, 2013
Received: February 6, 2013

Dear Mr. Jeff D. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram Zuckerman
Director of Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K124061

Device Name: MRI Patient Monitoring System (Model 865214)

Indications for Use: The MRI Patient Monitoring System (Model 865214) is intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The MRI Patient Monitoring System (Model 865214) is intended for use by healthcare professionals.

Prescription Use: X AND/OR Over-the Counter Use: _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S

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